

Translation

PATENT COOPERATION TREATY

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PCT/EP2003/010104



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 3970164WO ste/neg	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/010104	International filing date (day/month/year) 11 September 2003 (11.09.2003)	Priority date (day/month/year) 17 September 2002 (17.09.2002)
International Patent Classification (IPC) or national classification and IPC A61B 17/80		
Applicant DEPUY SPINE SARL		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 15 April 2004 (15.04.2004)	Date of completion of this report 27 December 2004 (27.12.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages _____ 1-11 _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____ 1-9 _____, filed with the letter of _____ 01 July 2004 (01.07.2004)
- ☒ the drawings:
pages _____ 1/3-3/3 _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-9	YES
	Claims		NO
Inventive step (IS)	Claims	1-9	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims		NO

2. Citations and explanations

1. DE-A-19950270 (D1), which is considered to represent the closest prior art in relation to the subject matter of claim 1, discloses (the references in parentheses are to this document):

A system for osteosynthesis with

- a vertebra plate (see column 2, line 47) with at least two receiving orifices 24, 26 for receiving the screw heads of bone screws which are suitable for fastening the vertebra plate to two vertebrae, wherein the receiving orifices have a corrugation 28, 32, in particular a longitudinal corrugation, in the distal area across their circumference, wherein the depth of the corrugation increases from the proximal to the distal end (see figures 1 and 2), and
- a bone screw (see column 1, line 36; column 2, lines 27-29 and 63-68; column 3, lines 22-26) with a screw head and a threaded screw shank (implicitly disclosed), wherein the screw head has a corrugation, in particular a longitudinal corrugation, on its outer circumference, wherein the corrugation viewed over its length varies in

depth (see serration, column 3, line 24, which may match the serration 32 of the receiving orifice 26) and the screw head is substantially spherical (see column 2, line 63: "configured like a ball").

The subject matter of claim 1 differs from the system known from D1 in that

- the vertebra plate is a cervical vertebra plate, and that
- the depth of the corrugation increases from the poles in the direction of the great circle.

Although DE-A-4409833 (D4) discloses a bone screw for fastening a cervical vertebra plate that has a corrugation (serration 23 in figure 4), the depth of which increases from the poles in the direction of the great circle of the substantially spherical screw head, the serration 23 in D4 cooperates, not with a counter-corrugation (not present) in the receiving orifices of the plate, but with separate detent elements 15. Consequently, a person skilled in the art would not transfer the features known from D4 to D1 in order to provide more secure fixation of the bone screws in the vertebra plate. The remaining citations in the search report are also incapable of suggesting, in combination with D1, the subject matter of claim 1.

Claim 1 therefore meets the requirements of PCT Article 33(2) and (3).

2. Claims 2-9 are dependent on claim 1 and therefore

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likewise meet the PCT requirements for novelty (PCT Article 33(2)) and inventive step (PCT Article 33(3)).

3. Pursuant to PCT Rule 6.3(b), claim 1 should have been drafted in the two-part form and delimited over D1.